

Appln. No. 10/630,926  
Amd. dated June 19, 2006  
Reply to Office Action of January 25, 2006

**REMARKS**

The Office Action has been carefully reviewed. No claim is allowed. Claims 3, 4, 17-19 and 21 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The rejection of claims 3, 4 and 17-19 under 35 U.S.C. §112, first paragraph, has been maintained. This rejection is respectfully traversed.

Claim 3 is amended to recite a transgenic mouse having a fully supported and specific phenotype (the expression of GILZ resulting in a significant decrease in CD4<sup>+</sup> CD8<sup>+</sup> double positive, and increase in CD4<sup>-</sup> CD8<sup>-</sup> double negative, CD8<sup>+</sup> single positive and CD4<sup>+</sup> single positive cells in the transgenic mouse when compared with a non-transgenic mouse) as suggested by the examiner. Support for such a phenotype can be found, for example, at page 84, paragraph [00278] of the application as filed. The property that GILR induces an enhanced activation of the caspase 3 pathway is however not recited in the claims. As stated on page 84, paragraph [00278] of the present specification, the specific phenotype observed is a consequence of the GILR-enhanced activation of the caspase 3 activation pathway. The specific phenotype of the mouse is therefore the

decrease in CD4<sup>+</sup> CD8<sup>+</sup> double positive, and increase in CD4<sup>-</sup> CD8<sup>-</sup> double negative, CD8<sup>+</sup> single positive and CD4<sup>+</sup> single positive cells as compared to a non-transgenic mouse (this being due to GILR-enhanced activation of caspass 3 activation pathway). Therefore, the recitation of the activation of the caspase 3 pathway in the claims is not necessary and would be redundant.

Applicants submit that in view of these limitations, the amended set of claims defines an invention that is fully enabled. As argued in the reply to the previous Office Action, the present specification provides ample enablement for the claimed transgenic mouse. The specification discloses at page 63, lines 17-19, the "mammalian T-cell lineage specific promoter" that can be used in the present context. More specific description of known mammalian T-cell lineage specific promoters can be found in the paragraph bridging pages 63 and 64. Applicants have disclosed a list of selected promoters that are known to be T-cell lineage-specific promoters. Moreover, the sequences of these promoters are known as well as the procedures to isolate them and to operably link them to the claimed cDNA. Example 2 of the present specification discloses a specific example of the presently claimed transgenic mice in detail. The mammalian T-cell lineage specific promoter used in this example is the human CD2 promoter.

The present specification also discloses mammalian GILR (GILZ) cDNA sequences. A general description of the GILR cDNA sequences can be found, for example, at page 12, paragraph 29 of the specification. More specific disclosure of two mammalian GILR cDNA sequences, the mouse and human sequences, is found in paragraphs 29 and 30 (Fig. 2 and SEQ ID NOs:1 and 5). As mentioned above, Example 2 of the present specification provides a specific example of the presently claimed transgenic mice where the mammalian GILR cDNA sequence used in the example is the mouse GILR cDNA.

Coupled with the general knowledge in the art at the time the present invention was made, sufficient guidance is provided by the present specification to one of skill in the art to use the presently claimed invention without undue experimentation. MPEP 2164.01 states, that:

The fact that the experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation, *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. Sub nom., Massachusetts Institute of Technology v A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Accordingly, one of skill in the art is well enabled for the full scope as presently claimed.

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Reconsideration and withdrawal of the rejection are  
therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C.  
§112 and define patentable subject matter warranting their  
allowance. Favorable consideration and early allowance are  
earnestly urged.

Respectfully submitted,

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